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*Original Research Article*

# Procedural Outcomes Analysis of Endoscopic Retrograde Cholangiopancreatography Procedures at Tertiary Centre Hospital in South India

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## ABSTRACT

**Background and aims:** Endoscopic retrograde cholangiopancreatography (ERCP) is used in the treatment of benign and malignant pancreatic and biliary diseases. The study was to determine indications, success rates and complications of ERCP procedures in a tertiary care centre in South India.
**Methods:** Retrospective data from patients undergoing ERCP procedures were analysed from August 2015 to July 2016. The demographic data, indications, the findings, the outcome in terms of technical success, cannulation rate, therapeutic procedures and complications were all collected and analyzed.
**Results:** Total 261 procedures were done during study period. Mean age 52 years (range17-89). Male: female 1.34:1. Most common indication was choledocholithiasis, malignant strictures, in pancreatic procedures most common was chronic pancreatitis. All procedures were done under conscious sedation. Successful cannulation in desired duct was 90.2%.Technical success was achieved in 85%. Most failed procedures were of grade 3 in difficulty. Overall complication occurred in 8% patients including pancreatitis, cholangitis, perforation, bleeding. One death (0.3%) was reported.
**Conclusion:** Ours is a high volume referral centre for ERCP procedures with more than 200 procedures in one year. Malignancy is common indication for ERCP procedure. Its indications and complications in our centre are similar to those reported from other centres.

***Keywords:*** ERCP, outcome, complication.

## INTRODUCTION

ERCP procedure is defined as any endoscopic procedure with an intention to cannulate the common bile duct (CBD) or the pancreatic duct. The most common therapeutics in ERCP is stent insertions for biliary obstruction and removal of common bile duct (CBD) stones. Diagnostic procedures now are avoided, because availability of non-invasive magnetic resonance imaging (MRI/MRCP) or endoscopic ultrasound (EUS). The quality indicators of ERCP practice include proper indications and low complication rate as well as success rate of desired duct cannulation. [(1)] Main complications are pancreatitis, haemorrhage, cholangitis and perforation. [(2,3)] In this study, our aim was to retrospectively investigate indications,

success rates and complications of ERCPs in a high-volume referral hospital.

## METHODS

This is a retrospective study done at a single centre from India .We are a tertiary care referral centre located in South India. The ERCP documentation files of all the patients from 1st August 2015 to 31st July 2016 were retrieved. All procedures performed by three experienced endoscopists. Written informed consent was taken before procedures. All complications were managed in our hospital .All procedures were done in conscious sedation. Olympus duodenoscopes were used in all procedures. Method of entering the bile duct was to use sphincterotome or to cannulate over guide wire inserted in the CBD. Outcome was analysed using indications, cannulation rates, therapeutic procedure success rates and complications .Malignancy was diagnosed based on clinical, radiological and pathological basis. Complications were classified using the standardised criteria proposed by Cotton et al. [(4)] Technical success was defined by removal of stone, placement of stents or completion of therapeutic target and was analysed with degree of difficulty based on ASGE guidelines. [(1)] SPSS 17 version was employed for data analysis.

## RESULTS

Total no of procedures in one year were 261. Males: n= 152 (58.2%) Females: n =109 (41.7%).Mean age: 52 yrs (range 17-89).

Indications for ERCP procedures are listed in Table 1. Most common indication was choledocholithiasis (n=97, 37.63%). Malignant obstructive jaundice was seen in 94 patients (36.01%). Among them 54 patients had cholangiocarcinoma, 20 patients had periampullary carcinoma, 13 pateints had carcinoma head of pancreas and 7 patients were having carcinoma gall bladder with CBD infiltration.

In the present study the successful cannulation of desired duct was done in 235 (90.2%) of all ERCP procedures. The complexity and difficulty level of completed ERCP procedures were graded by a three-step classification. Technical success of procedure was achieved in 222 (85.05%) procedures. ERCPs procedures fell into categories I, II and III with 130, 78 and 14 respectively (Table 2).

**Table 1-Indications of ERCP procedures.**

| Indications of ERCP procedures | No of procedures n =261 (%) |
|---|---|
| CBD stones | 97 (37.16%) |
| Cholangiocarcinoma | 54 (20.68%) |
| Benign strictures | 44 (16.8%) |
| Periampullary carcinoma | 20 (7.6%) |
| Chronic pancreatitis | 13 (4.9%) |
| Pancreatic head carcinoma | 13 (4.9%) |
| Post operative biliary leak | 7 (2.6%) |
| Gall bladder carcinoma | 7 (2.6%) |
| Recurrent pancreatitis diagnosis | 4 (1.5%) |
| Pancreatic duct leak | 4(1.5%) |
| Pseudocyst compression biliary tract | 3 (1.1%) |
| Portal biliopathy | 3 (1.1%) |
| Hydatid cyst communication | 2 (0.76%) |
| Liver abscess communication | 1 (0.38%) |
| Biliary Ascariasis | 1 (0.38%) |
| Total | 261 |

**Table no 2- Endoscopic retrograde cholangio-pancreatography (ERCP) technical success and difficulty grading of ERCP**

| ERCP procedures Degree of Difficulty (18) | No of procedures N=261 | Technical Success (n) | Chi Square |
|---|---|---|---|
| Grade 1 Standard | 142(54%) | 130(91%) | |
| Grade 2 Advanced | 97 () | 78 (76%) | |
| Grade 3 Tertiary | 22 | 14(59%) | |
| Total | 261 | 222(85.05%) | P=0.549 |

Success rate of extraction of common bile duct stones <1 cm in patients with normal bile duct anatomy was done in 88 (90.7%) patients. In procedures for CBD stone extraction, complete stone removal was not possible due to large stones (>10mm) in 4 patients, concomitant stricture 3 patients, 1 patient was intolerant to pain hence procedure was abandoned. In pancreatic procedures failure for cannulation was due to altered anatomy of papilla in 4 patients and inflammatory changes seen in 2 patients. In other 2 patients with chronic pancreatitis, pancreatic

stent could not be successfully placed due stricture and stone.

Therapeutic procedures were 193 sphincterotomies (31.4%), 162 stent placements (26.6%), 78 balloon trawls (12.5%), 5 basket trawls (0.8%), 4 mechanical lithotripsies (0.6%), 22 balloon sphincteroplasties (3.5%),32 bougie dilatation (5.1%), 6 nasobiliary drain(0.9%), 54 brush cytology (8.6%), 23 bile culture sampling(3.6%), 43 biopsies (6.9%). Precut utilization for cannulation was 28 patients (10.8%), 24 for biliary cannulation (85.7%) and 4 for pancreatic cannulation (14.3%).

Complications (Table 3) were diagnosed within 24 hours of procedure, total complication occurred in 21 patients (8%). Pancreatitis was most common 8(2.2%) patients. Cholangitis occurred in 3 patients, and bleeding occurred in 3 patients .Perforation occurred in one patient with carcinoma gall bladder with infiltration in duodenum and biliary duct. Patient died within 48 hours of procedure patient had metastatic disease with comorbidity and was high risk for surgical procedure. Complication related to sedation occurred in 5 patients all patients were high risk patients with multiple comorbidities.

**Table 3 Complications of ERCP**

| Type of complications Total no of procedures (n261) | No of patients (%). | Consensus criteria 2002 |
|---|---|---|
| Pancreatitis | 8 (3.06%) | Mild -6 Moderate-2 Severe-0 |
| Cholangitis | 3(1.14%) | Mild-2 Moderate-1 Severe-0 |
| Perforation | 2 (0.76%) | Mild-1 Moderate-0 Severe-1 |
| Bleeding | 3 (1.14%) | Mild-2 Moderate-1 Severe-0 |
| Cardiopulmonary failure | 3 (1.14%) | |
| Aspiration | 2(0.76%) | |
| Total | 21(8.04%) | |
| Death | 1 | |

## DISCUSSION

ERCP is a technically demanding invasive procedure with a risk of serious complications, ERCP practice should be critically evaluated in terms of indications, success rates and complications. [(1)] Most of the earlier studies come from western developed countries, whereas there are a few reports from developing countries. [(5)] Our objective was to describe ERCP-practice in developing country like India and to report success rates and complication figures that could be compared to earlier literature from developed nations with state of art centres and technology.

In most literature, most common indication for ERCP procedure is removal of CBD stones, varying from 30% to 75% of total procedures. [(6,7)] But we have comparatively less of these procedures as most are done by peripheral hospitals in India.

In the present study the success rate of cannulation was 90 .2% of all ERCPs .Studies from academic centres have reported successful bile duct cannulation in 85.6–98.1% of cases. [(5,8,11)] ASGE quality statement for priority states that cannulation rates should be more than 90% and stone removal <10mm with normal anatomy more than 90%. [(10)] In our study both the quality indicators were fulfilled. In UK a study showed that grade I,II,III degree of 4. Difficulties were 92%, 7.3%, 0.7%. This difference may be due to the referral protocols. [(9)]

Complications in large series, between 2% and 7% of procedures are followed by pancreatitis. [(13-16)] However, in randomised trials, where the reporting may be more accurate, 8-15% of procedures are associated with this complication. [(12,17-19)] Haemorrhage occurs in 0.5-2% of patients undergoing ERCP. [(16,17,21)] This complication is, as expected, related to sphincterotomy or pre-cut. [(21,22)] Most of the large studies report that between 0.5% and 2% of ERCPs are complicated by cholangitis. [(16,23,24)]

Perforation is the least common complication of ERCP. [(25)] Large series report that between 0.1% and 1.8% of ERCPs are complicated by perforation. [(16,25-27)]

The mortality as a direct consequence of ERCP in the present study was 0.3%. This compares favourably with recently published data which reported a procedure-related mortality rate of 0.4 %. **(20)**

## CONCLUSION

In conclusion, our study showed that biliary disorders requiring ERCP are common problem in India. ERCP has a definite therapeutic role in treating these conditions but also carries a significant risk of morbidity and mortality. The indications and success rates as well as morbidity and mortality from our centre are acceptable compared to those in earlier reports and published guidelines. More prospective and population studies are needed to explain high number of cholangiocarcinoma reported by us.

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